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MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.

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EXAMINER

WOLF, MEGAN YARNALL

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,938

Applicant(s)

MENICANTI ET AL.

Examiner

Megan Wolf

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 7, 10, 12-18, 21-24, 26, 27, 37 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 14-18, 21-24, 26, 27 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7, 10, 12, 13 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 040805
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species 1A and 1B in the reply filed on 2/4/09 is acknowledged. Claims 14-18, 21-24, 26, 27, and 37 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3, 4, 7, 10, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Lines 7 and 8 of claim 1 state "wherein reducing the diameter of the opening in the distal end of the retractor reduces *the diameter*". It is unclear whether "the diameter" is referring to the diameter of the annulus, the diameter of the opening in the distal end of the retractor, or another diameter. Please clarify.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Seguin 6,461,366. Seguin discloses a method for reducing a size of a mitral valve annulus, comprising positioning at least a portion of a retractor 1 substantially adjacent a portion of a circumference of the annulus, coupling one or more of a plurality of extendable members 4 of the retractor to the portion of the circumference, reducing the diameter of an opening in the distal end of the retractor, wherein the opening is at least partially defined by the portion of the retractor coupled to the portion of the circumference, and wherein reducing the diameter of the opening in the distal end of the retractor reduces the diameter, and positioning at least a portion of one or more fasteners 5 in the portion of the circumference to inhibit deformation of the reduced diameter of the portion of the circumference of the mitral valve annulus (figs.5-9; col.3, ll.43-47; col.4, ll.27-34). Seguin further discloses a retractor comprising conduit 2 with extendable members 4 that are positionable in the conduit wherein extending and retracting the extendable members results in an increase and decrease in the corresponding diameter respectively (col.3, ll.41-46; figs.7 and 8). The retractor may also include depressions on the distal ends of the extendable members, considered the underside of trumpeted distal ends 40a (fig.11), as well as vacuum through openings (col.4, ll.46-52).

6. Claim 43 is rejected under 35 U.S.C. 102(e) as being anticipated by Liddicoat et al. 6,702,826. Liddicoat discloses a method for reducing a size of a mitral valve annulus, comprising positioning at least a portion of an inactivated fastener substantially in a

portion of a circumference of the annulus, activating the inactivated fastener reducing the diameter of the portion of the circumference, wherein the activated fastener inhibits deformation of the reduced diameter of the portion of the circumference of the mitral valve annulus (col.9, ll.26-54; figs.1-4, 22-24).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seguin 6,461,366 in view of Carter et al. 2001/0056283. Seguin discloses the invention substantially as claimed but does not disclose that the depression positioned toward the end of the outer surface of the extendable members comprises one of more surface irregularities.

Carter teaches a retractor, in the same field of endeavor, wherein the distal ends comprise serrations 196 for the purpose of increasing friction between the tissue and the tool resulting in better adherence during grasping (par.144).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the ends of the retractor disclosed by Seguin to include surface irregularities as taught by Carter in order to increase the amount of friction between the ends and tissue and thereby improving the grasp on the tissue.

Allowable Subject Matter

9. Claims 7, 12, and 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738